

Form PTO-1449 (modified)	Atty. Docket No.: NANO:002USD1	Serial No.: 10/072,320
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)	Applicant: Russell Mumper Michael Jay	
	Filing Date: February 7, 2002	Group: 1618
U.S. Patent Documents <i>See Pages 1-2</i>	Foreign Patent Documents <i>See Page 2</i>	Other Art <i>See Pages 2-9</i>

### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A3	2002-0142042	10/3/02	Mumper <i>et al.</i>	424	434	12/27/00
	A4	3,922,260	11/25/75	Peniston <i>et al.</i>	260	211	08/24/73
	A5	4,552,751	12/12/85	Inaba <i>et al.</i>	424	449	10/19/81
	A6	4,900,554	2/13/90	Yanagibashi <i>et al.</i>	424	448	12/23/87
	A7	5,081,157	2/14/92	Pomerantz	514	781	2/6/91
	A8	5,081,158	1/14/92	Pomerantz	514	781	3/8/90
	A9	5,102,666	4/792	Acharya	424	487	9/11/90
	A10	5,192,802	3/9/93	Rencher	514	535	9/25/91
	A11	5,252,318	10/12/93	Joshi <i>et al.</i>	424	78.04	06/15/90
	A12	5,298,258	3/29/94	Akemi <i>et al.</i>	424	484	6/16/92
	A13	5,314,915	5/24/94	Rencher	514	535	12/16/92
	A14	5,346,701	09/13/94	Heiber <i>et al.</i>	424	435	02/22/93
	A15	5,362,737	11/8/94	Vora <i>et al.</i>	514	291	1/19/93
	A16	5,441,732	08/15/95	Hoeg <i>et al.</i>	424	78.04	03/18/92
	A17	5,446,070	08/29/95	Mantelle, Juan A.	514	772.6	8/27/93
	A18	5,472,704	12/05/95	Santus <i>et al.</i>	424	435	12/27/93
	A19	5,639,469	06/17/97	Benes <i>et al.</i>	424	435	06/15/94
	A20	5,688,520	11/18/97	Karsenty <i>et al.</i>	424	434	05/24/95
	A21	5,780,045	07/14/98	McQuinn <i>et al.</i>	424	434	11/08/96
	A22	5,800,832	9/1/98	Tapolsky <i>et al.</i>	424	449	10/18/96
	A23	5,900,247	05/04/99	Rault <i>et al.</i>	424	434	12/27/96
	A24	5,955,097	9/21/99	Tapolsky <i>et al.</i>	424	434	10/18/96
	A25	5,989,535	11/23/99	Nayak	424	78.02	08/15/97

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	A26	5,993,846	11/30/99	Friedman <i>et al.</i>	424	434	04/21/98
	A27	6,004,546	12/21/99	Sachetto	424	78.01	05/14/99
	A28	6,086,911	07/11/00	Godbey	424	448	06/16/98
	A29	6,159,498	12/12/00	Tapolsky <i>et al.</i>	424	449	09/01/98
	A30	6,210,699	04/03/01	Acharya <i>et al.</i>	424	435	04/01/99
	A31	6,319,510	11/20/01	Yates	24	04	2/22/00

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language
	B5	AU 754490	10/18/99	Australia	English
	B6	WO 00/54733	9/21/00	WIPO	German (English Abstract)

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Aspden <i>et al.</i> , "Chitosan as a nasal delivery system: Evaluation of the effect of chitosan on mucociliary clearance rate in the frog palate model," <i>Int. J. Pharm.</i> , 122:69-78, 1995.
	C2	Bayley <i>et al.</i> , "The transmucosal absorption of recombinant human interferon-alpha B/D hybrid in the rat and rabbit," <i>J. Pharm. Pharmacol.</i> , 47:721-724, 1995.
	C3	Bechgaard <i>et al.</i> , "Solubilization of various benzodiazepines for intranasal administration, a pilot study," <i>Pharm Dev Tech</i> , 2:293-296, 1997.
	C4	Berthold <i>et al.</i> , "Preparation and characterization of chitosan microspheres as drug carrier for prednisolone sodium phosphate as model for anti-inflammatory drugs," <i>J. Cont. Rel.</i> , 39:17-25, 1996.
	C5	Binnie <i>et al.</i> , "Amlexanox oral paste: a novel treatment that accelerates the healing of aphthous ulcers," <i>Compend Contin Educ Dent</i> , 18:1116-1118, 1997.

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	C6	Bodde <i>et al.</i> , "Mucoadhesive polymers for the buccal delivery of peptides, structure-adhesiveness relationships," <i>J. Cont. Rel.</i> , 13:225-231, 1990.
	C7	Casetta and Negretti, "Salivary immune responses after gingival immunization with tetravaccinal and bivaccinal formulations of inactivated micro-organisms," <i>Dev Biol Stand</i> , 92:317-321, 1998.
	C8	Chang, "Stability of hirudin, a thrombin-specific inhibitor," <i>J Biol Chem</i> , 266:10839-10843, 1991.
	C9	Duchene <i>et al.</i> , "Pharmaceutical and medical aspects of bioadhesive systems for drug administration," <i>Drug Devol. Ind. Pharm.</i> , 14:283-318, 1988.
	C10	Eric and Caroline, "Influence of storage conditions on the activity of recombinant hirudin," <i>Thromb Res</i> , 61:87-89, 1991.
	C11	Eriksson <i>et al.</i> , "Prevention of thromboembolism with use of recombinant hirudin. Results of a double-blind, multicenter trial comparing the efficacy of desirudin (Revasc) with that of unfractionated heparin in patients having a total hip replacement," <i>J Bone Joint Surg Am</i> , 79:326-333, 1997.
	C12	Esslinger <i>et al.</i> , "Pharmacodynamic and safety results of PEG-hirudin in healthy volunteers," <i>Throm Haemost</i> , 77:911-919, 1997.
	C13	Etchart <i>et al.</i> , "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus hemagglutinin," <i>J Gen Virol</i> , 78:1577-1580, 1997.
	C14	Fenton <i>et al.</i> , "Thrombin inhibition by hirudin: how hirudin inhibits thrombin," <i>Haemostasis</i> , 21:27-31, 1991.
	C15	Fenton, "Thrombin interactions with hirudin," <i>Sem Thromb Hemost</i> , 15:265-268, 1989.
	C16	Garcia-Closas <i>et al.</i> , "Epidemiologic determinants of vaginal pH," <i>Am J Obstet Gynecol</i> , 180:1060-1066, 1999.
	C17	Goto <i>et al.</i> , "Preparation and evaluation of Eudragit gels. I: Eudragit organogels containing drugs as rectal sustained-release preparations," <i>J. Pharm. Sci.</i> , 80:958-961, 1991.
	C18	Hardy <i>et al.</i> , "Women's preferences for vaginal antimicrobial contraceptives. III. Choice of a formulation, applicator, and packaging," <i>Contraception</i> , 58:245-249, 1998a.
	C19	Hardy <i>et al.</i> , "Women's preferences for vaginal antimicrobial contraceptives. IV. Attributes of a formulation that would protect from STD/AIDS," <i>Contraception</i> , 58:251-255, 1998b.

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	C20	Harris and Robinson, "Bioadhesive polymers in peptide drug delivery," <i>Biomaterials</i> , 11:652-658, 1990.
	C21	Heath <i>et al.</i> , "Mechanism of triclosan inhibition of bacterial fatty acid synthesis," <i>J Biol Chem</i> , 274:11110-11114, 1999.
	C22	Henriksen <i>et al.</i> , "Interactions between liposomes and chitosan II: effect of selected parameters on aggregation and leakage," <i>Int. J. Pharm.</i> , 146:193-204, 1997.
	C23	Hjortkjaer <i>et al.</i> , "Single- and repeated-dose local toxicity in the nasal cavity of rabbits after intranasal administration of different glycols for formulations containing benzodiazepines," <i>J Pharm Pharmacol</i> , 51:377-383, 1999.
	C24	Illum <i>et al.</i> , "Chitosan as a novel nasal delivery system for peptide drugs," <i>Pharm. Res.</i> , 11:1186-1189, 1994.
	C25	Imai <i>et al.</i> , "Interaction of indomethacin with low molecular weight chitosan, and improvements of some pharmaceutical properties of indomethacin by low molecular weight chitosans," <i>Int. J. Pharm.</i> , 67:11-20, 1991.
	C26	International Preliminary Examination Report issued in International Application No. PCT/US01/49524, completed February 24, 2004.
	C27	International Search Report issued in International Application No. PCT/US01/49524, mailed January 24, 2003.
	C28	Jones <i>et al.</i> , "Targeting and delivery of bactericide to adsorbed oral bacteria by use of proteoliposomes," <i>Biochim Biophys Acta</i> , 1147:251-261, 1993.
	C29	Kawata <i>et al.</i> , "Preparation and evaluation of Eudragit gels. II: In vitro release of salicylic acid, sodium salicylate, and ketoprofen from Eudragit L and S organogels," <i>J. Pharm. Sci.</i> , 80:1072-1074, 1991.
	C30	Khan <i>et al.</i> , "A pH-dependent colon targeted oral drug delivery system using methacrylic acid copolymers. I. Manipulation of drug release using Eudragit L100-55 and Eudragit S100 combinations," <i>J. Controlled Release</i> , 58:215-222, 1999.
	C31	Khandwala <i>et al.</i> , "5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: II. Pharmacokinetics and demonstration of clinical safety," <i>Oral Surg Oral Med Oral Pathol Oral Radiol Endod</i> , 83:231-238, 1997b.

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	C32	Khandwala <i>et al.</i> , "5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: I. clinical demonstration of acceleration of healing and resolution of pain," <i>Oral Surg Oral Med Oral Pathol Oral Radiol Endod</i> , 83:222-230, 1997a.
	C33	Kim <i>et al.</i> , "Preparation and evaluation of Eudragit gels. III: Rectal gel preparations for sustained release of pentoxifylline," <i>J. Pharm. Sci.</i> , 81:537-540, 1992.
	C34	Kim <i>et al.</i> , "Preparation and evaluation of Eudragit gels. IV: Rectal gel preparations for sustained release and avoidance of first-pass metabolism of propentofylline," <i>J. Pharm. Sci.</i> , 81:904-907, 1992.
	C35	Kim <i>et al.</i> , "Preparation and evaluation of eudragit gels. V. Rectal gel preparations for sustained release and avoidance of first-pass metabolism of lidocaine," <i>Chem. Pharm. Bull</i> , 40:2800-2804, 1992.
	C36	Lehr <i>et al.</i> , "In vitro evaluation of mucoadhesive properties of chitosan and some other natural polymers," <i>Int. J. Pharm.</i> , 78:43-48, 1992.
	C37	Leopold and Eikeler, "Eudragit E as a coating material for the pH-controlled drug release in the topical treatment of inflammatory bowel disease (IBD)," <i>J Drug Targeting</i> , 6:85-94, 1998.
	C38	Leung <i>et al.</i> , "Mucoadhesive dosage forms for peptide and protein drug delivery," In: <i>Peptide and Protein Drug Delivery</i> , V.H.L. Lee ed. Marcel Dekker, Inc. New York, pp. 741-767, 1991.
	C39	Li <i>et al.</i> , "In vitro release and permeation of oxytocin from a mucoadhesive buccal patch," <i>Pharm. Dev. Technol.</i> , 1:357-364, 1996.
	C40	Li <i>et al.</i> , "Transmucosal delivery of oxytocin to rabbits using a mucoadhesive buccal patch," <i>Pharm. Dev. Technol.</i> , 2:265-274, 1997.
	C41	Liu <i>et al.</i> , "DNA vaccines: A new era in vaccinology," <i>Ann NY Acad Sci, New York, NY</i> , 772. 1995.
	C42	Loftsson <i>et al.</i> , "Effect of cyclodextrins and polymers on triclosan availability and substantivity in toothpastes in vivo," <i>J Pharm Sci</i> , 88:1254-1258, 1999.
	C43	MacLaughlin <i>et al.</i> , "Chitosan and depolymerized chitosan oligomers as condensing carriers for in vivo plasmid delivery," <i>J. Controlled Rel.</i> , 56:259-272, 1998.
	C44	Mandel, "Antimicrobial mouthrinses: overview and update," <i>J Am Dent Assoc</i> , 125:2S-10S, 1994.

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	C45	March and Nakamura, "Evaluation of the duration of effect of a bioadhesive vaginal moisturizing gel on vaginal pH," 7 <sup>th</sup> International Congress on the Menopause, Replens Symposium, Stockholm, Sweden, June 20-22, 1993.
	C46	Markwardt, "Development of hirudin as an antithrombotic agent," <i>Sem Thromb Hemost</i> , 15:269-282, 1989.
	C47	Markwardt, "Past, present and future of hirudin," <i>Haemostasis</i> , 21:11-26, 1991b.
	C48	Markwart, "Hirudin and derivatives as anticoagulant agents," <i>Thromb Haemost</i> , 66:141-152, 1991a.
	C49	Martin <i>et al.</i> , <i>Martin's Physical Pharmacy: Physical chemical principles in the pharmaceutical sciences</i> , Lea & Febiger, Third Ed., Philadelphia, 1983.
	C50	McGhee and Kiyono, "Mucosal immunity to vaccines: Current concepts for vaccine development and immune response analysis," In: <i>J.E. Ciaridi (ed.) Genetically engineered vaccines</i> , Plenum Press, New York, NY, pp. 3-12, 1992a.
	C51	Meshali and Gabr, "Effect of interpolymer complex formation of chitosan with pectin or acacia on the release behavior of chlorpromazine HCl," <i>Int. J. Pharm.</i> , 89:177-181, 1993.
	C52	Nakamura <i>et al.</i> , "Uptake and release of budesonide from mucoadhesive, pH-sensitive copolymers and their application to nasal delivery," <i>J Control Release</i> , 61(3):329-35, 1999.
	C53	Office Action issued in Canadian Application No. 2,437,150, mailed August 15, 2008.
	C54	Office Action issued in European Application No. 01 991 430.8, mailed October 2, 2008.
	C55	Office Action issued in European Application No. 01 991 430.8, mailed December 4, 2006.
	C56	Office Action issued in U.S. Application No. 09/748,133, mailed November 16, 2001
	C57	Office Action issued in U.S. Application No. 09/748,133, mailed May 8, 2002.
	C58	Office Action issued in U.S. Application No. 09/748,133, mailed December 18, 2002
	C59	Office Action issued in U.S. Application No. 09/748,133, mailed December 30, 2003.
	C60	Office Action issued in U.S. Application No. 09/748,133, mailed September 13, 2006.
	C61	Office Action issued in U.S. Application No. 09/748,133, mailed March 1, 2007.

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	C62	Office Action issued in U.S. Application No. 09/748,133, mailed September 20, 2007.
	C63	Office Action issued in U.S. Application No. 09/748,133, mailed February 21, 2008.
	C64	Office Action issued in U.S. Application No. 09/748,133, mailed September 4, 2008.
	C65	Park and Robinson, "Mechanisms of mucoadhesion of poly(acrylic acid) hydrogels," <i>Pharm Res</i> , 4(6):457-64, 1987.
	C66	Park and Robinson, "Physico-chemical properties of water insoluble polymers important to mucin/epithelial adhesion," <i>J Cont Rel</i> , 2:47-57, 1985.
	C67	Ramkissoo-Ganorkar <i>et al.</i> , "Effect of molecular weight and polydispersity on kinetics of dissolution and release from pH/temperature-sensitive polymers," <i>J Biomater Sci Polym Ed</i> 10(10):1149-61, 1999.
	C68	Rathbone <i>et al.</i> , In: <i>Oral J Mucosal Drug Delivery</i> , M.J. Rathbone Ed., Marcel Dekker Inc., New York, 1996.
	C69	<i>Remington's Pharmaceutical Sciences</i> , 18 <sup>th</sup> Ed., A.R. Gennard, ed. Mack Publishing Company, Easton, PA, 1990.
	C70	Riehl-Bellon <i>et al.</i> , "Purification and biochemical characterization of recombinant hirudin produced by <i>Saccharomyces cerevisiae</i> ," <i>Biochemistry</i> , 28:2941-2949, 1989.
	C71	Robinson and Torres, "C.A.T. DNA Vaccines," <i>Sem Immun</i> , 9:271-283, 1997.
	C72	Ryu <i>et al.</i> , "Increased bioavailability of propranolol in rats by retaining thermally gelling liquid suppositories in the rectum," <i>J Control Release</i> , 59(2):163-72, 1999.
	C73	Saijo <i>et al.</i> , "Inhibition by amoxanox (AA-673) of the immunologically, leukotriene D4- or platelet-activating factor-stimulated bronchoconstriction in guinea pigs and rats," <i>Int Arch Allergy Appl Immunol</i> , 77:315-321, 1985.
	C74	Saijo <i>et al.</i> , "The antiallergic agent amoxanox suppresses SRS-A generation by inhibiting lipooxygenase," <i>Int Arch Allergy Appl Immunol</i> , 79:231-237, 1986.
	C75	Sayani <i>et al.</i> , "Transmucosal delivery of leucine enkephalin: stabilization in rabbit enzyme extracts and enhancement of permeation through mucosae," <i>J. Pharm. Sci.</i> , 82:1179-1185, 1993.

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	C76	Schipper <i>et al.</i> , "Chitosans as absorption enhancers for poorly absorbable drugs. 1: Influence of molecular weight and degree of acetylation on drug transport across human intestinal epithelial (Caco-2) cells," <i>Pharm. Res.</i> , 13:1686-1692, 1996.
	C77	Schwagmeier <i>et al.</i> , "Midazolam pharmacokinetics following intravenous and buccal administration," <i>Br J Clin Pharmacol</i> , 46:203-206, 1998.
	C78	Scott <i>et al.</i> , "Buccal midazolam and rectal diazepam for treatment of prolonged seizures in childhood and adolescence: a randomised trial," <i>The Lancet</i> , 353:623-626, 1999.
	C79	Shiraishi <i>et al.</i> , "Controlled release of indomethacin by chitosan-polyelectrolyte complex: optimization and in vivo/in vitro evaluation," <i>J. Cont. Rel.</i> , 25:217-225, 1993.
	C80	Spannagl <i>et al.</i> , "A fast photometric assay for the determination of hirudin," <i>Haemostasis</i> , 21:36-40, 1991.
	C81	Stevens-Simon <i>et al.</i> , "Racial variation in vaginal pH among healthy sexually active adolescents," <i>Sex Transm Dis</i> , 21:168-172, 1994.
	C82	Takayama <i>et al.</i> , "Effect of interpolymers complex formation on bioadhesive property and drug release phenomenon of compressed tablet consisting of chitosan and sodium hyaluronate," <i>Chem. Pharm. Bull.</i> , 38:1993-1997, 1990.
	C83	Takeuchi <i>et al.</i> , "Enteral absorption of insulin in rats from mucoadhesive chitosan-coated liposomes," <i>Pharm. Res.</i> , 13:896-901, 1996.
	C84	Tang <i>et al.</i> , "Genetic immunization is a simple method for eliciting an immune response," <i>Nature</i> , 356:152-154, 1992.
	C85	Taubes, "Salvation in a snippet of DNA," <i>Science</i> , 278:1711-1714, 1997.
	C86	Ulmer <i>et al.</i> , "Toward the development of DNA vaccines," <i>Curr Opin Immunol</i> , 8:531-536, 1996a.
	C87	Umejima <i>et al.</i> , "Preparation and evaluation of Eudragit gels. VI: In vivo evaluation of Eudispert rectal hydrogel and xerogel containing salicylamide," <i>J. Pharm. Sci.</i> , 82:195-199, 1993.
	C88	Urisu <i>et al.</i> , "Inhibitory action of amlexanox on interleukin-3-induced enhancement of histamine releasability of human leukocytes," <i>Arerugi</i> , 39(10):1448-1454, 1990. (ABSTRACT)
	C89	Ward, "Direct thrombin inhibitors," <i>Stanford Interventional Cardiology</i> , 2000.

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List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant: Russell Mumper Michael Jay	
		Filing Date: February 7, 2002	Group: 1618
U.S. Patent Documents <i>See Pages 1-2</i>	Foreign Patent Documents <i>See Page 2</i>	Other Art <i>See Pages 2-9</i>	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C90	Wong <i>et al.</i> , "Formulation and evaluation of controlled release Eudragit buccal patches," <i>Int. J. Pharmaceutics.</i> , 178:11-22, 1999.
	C91	Yankauckas <i>et al.</i> , "Long-term anti-nucleoprotein cellular and humoral immunity is induced by intramuscular injection of plasmid DNA containing NP gene," <i>DNA Cell Biol.</i> , 12:771-776, 1993.
	C92	Zuckerbraun <i>et al.</i> , "Triclosan: cytotoxicity, mode of action, and induction of apoptosis in human gingival cells in vitro," <i>Eur J Oral Sci.</i> , 106:628-636, 1998.

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